

1 REMARKS

2 Status of the Claims

3 Claims 1, 2, 4-27, and 52-58 are pending in the present application, Claims 3 and 28-51
4 having been previously canceled, Claims 1, 4, 21, 27, 52, and 53 having been amended to correct
5 typographical errors, and Claims 54-58 having been added.

6 Amendment to the Title

7 The title has been amended to correct a typographical error.

8 Claims Rejected Under 35 U.S.C. § 103(a)

9 The Examiner has rejected Claims 1-2, 4-13, 18-27 and 52-53 under 35 U.S.C. §103(a) as
10 being unpatentable over Gain et al. (U.S. Patent No. 4,708,836 – hereinafter referred to as “Gain”)
11 and further in view of NPL #1, “Infant Skull Model and Sculpted Head” (retrieved on Jun 09, 2002).

12 In the interest of reducing the complexity of the issues for the Examiner to consider in this
13 response, the following discussion focuses on independent Claims 1, 21, 27, 52-54 and 57. The
14 patentability of each remaining dependent claim is not necessarily separately addressed in detail.
15 However, applicants’ decision not to discuss the differences between the cited art and each dependent
16 claim should not be considered as an admission that applicants concur with the Examiner’s conclusion
17 that these dependent claims are not patentable over the disclosure in the cited references. Similarly,
18 applicants’ decision not to discuss differences between the prior art and every claim element, or every
19 comment made by the Examiner, should not be considered as an admission that applicants concur with
20 the Examiner’s interpretation and assertions regarding those claims. Indeed, applicants believe that all
21 of the dependent claims patentably distinguish over the references cited. In any event, a specific
22 traverse of the rejection of each dependent claim is not required, since dependent claims are patentable
23 for at least the same reasons as the independent claims from which the dependent claims ultimately
24 depend.

25 Patentability of Independent Claim 1

26 Applicants respectfully submit that there is no motivation to modify the Gain reference to
27 include a simulated patent skull suture made from a second material, because Gain ignores such fine
28 anatomical structures and instead concentrates on approximating an appropriate hardness and
29 thickness of the artificial cranium. Further, even if Gain was modified to include the simulated patent
30 skull suture, applicants respectfully submit that the echogenicity of the second material would NOT

1 be substantially different than an echogenicity of the first material (in order to be distinguishable
2 from one another in an ultrasound image), but instead the second material would be so similar to the
3 first material that the materials could not be readily identified in an ultrasound image.

4 The Two Materials Disclosed by Gain

5 With respect to a first material, Gain discloses the cranium is made from an epoxy resin (the
6 Examiner has cited to column 5, lines 43-67 of Gain, which describes the artificial cranium).
7 Applicants note that this citation specifically references an epoxy resin.

8 With respect to a second material, Examiner cites to a second material used to simulate soft
9 tissues; the second material comprising a silicone elastomer (RHODOSIL RTV) that can be thinned
10 with oil to achieve silicone elastomers with a different durometer (i.e., a different hardness). Gain
11 teaches using softer elastomers (relatively more oil) for the eyes and harder elastomers (relatively less
12 oil) for cartilage.

13 The Examiner explains that although Gain does not state that the echogenicity of the epoxy is
14 substantially different than the echogenicity of the silicone elastomer, the Examiner has concluded
15 that the differences in density of the epoxy resin and the silicone elastomer would have resulted in a
16 difference in echogenicity such that the first and second material are distinguished in an ultrasound
17 image of said model. Applicants *strenuously* object to that conclusion, and respectfully point out that
18 the conclusion is entirely unsupported by any evidence.

19 Indeed, applicants' specification makes it clear that the conclusion is incorrect. Applicants'
20 simulator employs three different materials; two of which are generally similar and difficult to
21 discern using ultrasound, and one which can readily be distinguished from the other two materials
22 using ultrasound. Significantly, the two materials disclosed by applicants that are generally similar
23 and difficult to discern using ultrasound are *equivalent to the two materials disclosed by Gain.*

24 A first material disclosed by applicants is a polymer or plastic material used to form the
25 majority of the model. Applicants prior response provided a detailed analysis of the portions of the
26 specification defining the first material as a polymer (page 10, lines 3-12, the final paragraph on
27 page 10, and page 12, lines 19-31). The first material disclosed by Gain, epoxy resin, is a polymer,
28 and thus Gain's first material and applicants' first material are equivalent.

29 A second material disclosed by applicants is a mixture of starch and glue. Through empirical
30 observations, applicants determined that such a material could be added to a plastic model of a human

1 head, and the echogenicity of the first and second materials were so markedly different that the two
2 different materials could quite readily be distinguished in an ultrasound image. Significantly, Gain
3 does not teach or suggest any material equivalent to a starch/glue mixture.

4 A third material disclosed by applicants is a silicone elastomer (preferably dimethyl siloxane,
5 hydroxy-terminated polymers); i.e., a material that is equivalent to Gain's second material.
6 Significantly, applicants empirically determined that in an ultrasound image, polymers used to make
7 a model of a head, and silicone elastomers used to fill in simulated sutures, are **NOT** readily
8 distinguishable in an ultrasound image. Applicants' empirical studies indicated that some other
9 material (i.e., **NOT** a polymer and **NOT** a silicone elastomer) was needed to provide a material that
10 could be readily differentiated from a polymer and a silicone elastomer in an ultrasound image.

11 It appears that the Examiner assumed that because a polymer and a silicone elastomer are
12 likely to have different densities, such materials would be readily distinguishable in an ultrasound
13 image. Applicants' empirical studies have indicated that such an assumption is incorrect. Indeed,
14 applicants determined that because polymers and silicone elastomers are so difficult to distinguish in
15 an ultrasound image of a model of a human head, that silicone elastomer could be used to fill in a
16 simulated patent suture, such that in the ultrasound image the simulated suture would appear fused.
17 Applicants had to find yet another material (starch/glue) to fill an opening in the head model (the
18 opening simulating a patent skull suture), so that the fill material could be distinguished in an
19 ultrasound image. *Because applicants' empirical studies indicate that polymers and elastomers*
20 *appear similar in ultrasound images, there is no basis for concluding that adding oil to change the*
21 *hardness of the silicone elastomer would change the appearance of the silicone elastomer in an*
22 *ultrasound image enough to enable the silicone elastomer to be distinguishable from the polymer*
23 *model.*

24 It is also significant to note that the Examiner has objected to Claims 14-17 and 25, because
25 such claims recite a *third material* (the silicone elastomer) *that is distinguishable in an ultrasound*
26 *image from the second material* (the glue mixture), *but not the first material* (the polymer), *and* that
27 third material (a silicone elastomer) is equivalent to the *second* material disclosed by Gain. Therein
28 lies a logical contradiction that indicates the basis for rejecting the remaining claims is incorrect.

29 Clearly, including openings/sutures in Gain's cranium model and filling those openings with a
30 silicone elastomer would not achieve an equivalent to the subject matter claimed by applicants,

1 because such elastomers would be difficult to distinguish from the rest of the cranium. To achieve an
2 equivalent invention, the patent sutures would need to be filled with a material having an
3 echogenicity that is significantly different than the polymers and elastomers used by Gain (such as a
4 starch/glue mixture), and Gain does not teach or suggest such a material.

5 Modifying Gain to Include Patent Sutures

6 As noted above, applicants further submit that there is no motivation to modify Gain to
7 include simulated sutures, regardless of what material is used to fill those sutures. The Examiner
8 asserted that it would have been obvious to one of ordinary skill in the art to include the feature of
9 having simulated patent skull sutures as seen in NPL #1 in the Gain system, because it would enable
10 the Gain system to better approximate the physiology of a human infant.

11 Applicants respectfully disagree, because Gain does NOT emphasize that fine anatomical
12 details (such as sutures) are important in artificial craniums used for *mechanical tests for shock*
13 *resistance*. Gain notes that models suitable for the study of anatomy are not suitable for mechanical
14 crash studies. Gain indicates that what is needed is “an artificial cranium and a prosthetic head
15 produced from same cranium having the same mechanical behavior and shape characteristics as a
16 fresh cranium and a real head respectively” (column 1, lines 61-65). Gain further explains that
17 “shape characteristics” means that the artificial cranium must have the same shape and dimensions as
18 a real human cranium and also the cavities corresponding to the natural cavities of a real human
19 (column 2, lines 7-12). Gain also emphasizes determining equivalent resin thickness so that the
20 compression strength at a given point of the artificial cranium is equal to the compression strength at
21 the corresponding point of the fresh cranium (Gain, column 5, lines 57-62). But then Gain discloses
22 that the thickness of the material constituting the artificial cranium differs from that of the real bone
23 and that the internal cavities do not exactly reproduce the cavities of the fresh cranium, but Gain
24 indicates that these dimensional differences are not important so long as the mechanical properties
25 are faithfully replicated (Gain, column 5, lines 18-23). Thus, the approximate cranium mould 43
26 comprising a lower part 54 and an upper part 56 as seen in Gain’s FIGURE 5 used to produce the
27 artificial cranium is sufficient for purposes of accident prevention studies, and fine details of
28 anatomical structures are ignored.
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1 In other words, Gain does not teach or suggest that adding sutures to a cranium used for crash
2 studies would provide any benefit. Significantly, there is simply no evidence indicating that sutures
3 are at all relevant to the studies being performed by Gain.

4 Accordingly, Claim 1 and each claim dependent thereon patentably distinguish over the cited
5 art, and the rejection of Claims 1, 2, 4-13, and 18-20 under 35 U.S.C. § 103(a) should be withdrawn
6 (Claim 3 having been canceled).

7 Patentability of Independent Claim 21

8 Independent Claim 21 is directed toward a medical simulator adapted to be used to train
9 ultrasound operators to perform craniostynosis screenings using medical ultrasound, comprising a
10 substantially life size model of a human head. The Examiner has rejected Claim 21 for reasons
11 similar to those given in the rejection of Claim 1. Claim 21 therefore distinguishes over the cited art
12 for substantially the same reasons as does Claim 1.

13 Accordingly, the rejection of independent Claim 21 under 35 U.S.C. § 103(a) should be
14 withdrawn. Because dependent claims include all of the elements of the independent claim from which
15 the dependent claims ultimately depend, dependent Claims 22-24 are patentable for at least the reasons
16 discussed above in regard to independent Claim 21, and the rejection of dependent Claims 22-24 under
17 35 U.S.C. § 103(a) should also be withdrawn.

18 Patentability of Independent Claims 27

19 Independent Claim 27 is directed toward an ultrasound trainer configured to train ultrasound
20 operators to perform craniostynosis screenings using medical ultrasound; comprising a
21 substantially life size model of a human head, said model including at least one simulated patent skull
22 suture and at least one simulated fused skull suture. The Examiner has rejected Claim 27 for reasons
23 similar to those given in the rejection of Claim 1. In addition, the Examiner explains that although
24 Gain does not provide an explicit teaching where the second material is hypoechoic, that the
25 Examiner takes the position that the difference in density of the first material (epoxy resin) and the
26 second material (oil and silicon mixture) would result in the second material being hypoechoic with
27 respect to the first material. Therefore, it would follow that the portion of the model that corresponds
28 to the first material would appear relatively bright and portions of the model corresponding to the
29 second material appear relatively dark.

Applicants respectfully disagree. As indicated above, applicants' empirical studies using the second material disclosed by Gain (silicone elastomers) have clearly shown that silicone elastomers are not hypoechoic as compared to polymers used to form a model head. Therefore, the modification to Gain will not read on applicants' recitation of "each simulated patent skull suture will appear dark in such an ultrasound image" (because the silicone elastomer fill material will appear white in the ultrasound image, just as will the polymer forming the majority of the model, based on applicants' empirical studies using a polymer model and silicone elastomers). An entirely different material, such as a starch/glue mixture, is required. Claim 27 therefore distinguishes over the cited art for substantially the same reasons as does Claim 1.

Furthermore, Claim 27 specifically recites that the model must include *at least one simulated fused skull suture*. Even if Gain were modified to include patent skull sutures because such sutures represent fine anatomical detail that should be incorporated into a model used for crash testing (and as discussed above applicants submit that Gain **does not teach or suggest** that such fine anatomical details are needed), note that fused skull sutures represent an abnormality that appears to have no relationship to the crash testing for which Gain's model's are to be used. There are many different anatomical abnormalities possible in human heads, and Gain simply does not teach or suggest that a head model used for crash test purposes should include any such abnormality. To modify Gain's model to include **only** the abnormality recited in applicants' claims, an abnormality having nothing to do with crash testing, but which is very relevant to applicants' ultrasound screening, appears to impermissibly rely on hindsight. In other words, there does not appear to be any reasonable rationale for modifying Gain's model. Claim 27 therefore distinguishes over the cited art for this additional reason.

Accordingly, because the cited art does not teach or suggest the recitation of independent Claim 27, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn.

Patentability of Independent Claims 52 and 53

Independent Claim 52 is directed toward a medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life-size model of a human head, said model including two eyes, a mouth, two ears, and at least one simulated patent skull suture. Independent Claim 53 is directed toward a medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a

substantially life size model of a human head, said model including at least one simulated patent skull suture.

The Examiner has rejected Claims 52 and 53 for reasons similar to those given in the rejection of Claim 1. Claims 52 and 53 therefore distinguish over the cited art for substantially the same reasons as does Claim 1.

Accordingly, because the cited art does not teach or suggest the recitation of independent Claims 52-53, the rejection of independent Claims 52-53 under 35 U.S.C. § 103(a) should be withdrawn.

Allowable Subject Matter

The Examiner has objected to Claims 14-17 and 25 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have added new independent Claims 54 and 57 to rewrite some of the objected to claims in independent form, as discussed below.

Patentability of Independent Claim 54 and Claims Dependent Thereon

Independent Claim 54 generally includes the recitation of independent Claim 1 and the recitation of dependent Claims 12 and 14. Claim 14 is one of the claims the Examiner objected to as including allowable subject matter and indicated would be allowable if rewritten in independent form including all of the limitations of the base claim (i.e. Claim 1) and any intervening claims (i.e. Claim 14). In addition, dependent Claim 55 generally includes the recitation of Claim 15 and dependent Claim 56 generally includes the recitation of Claim 16. Thus, applicants respectfully submit that Claim 54 and its dependent claims are now in condition for allowance.

Patentability of Independent Claim 57 and Claims Dependent Thereon

Independent Claim 57 generally includes the recitation of independent Claim 21 and the recitation of dependent Claims 23 and 25. Claim 25 is one of the claims the Examiner objected to as including allowable subject matter and indicated would be allowable if rewritten in independent form including all of the limitations of the base claim (i.e. Claim 21) and any intervening claims (i.e. Claim 23). Thus, applicants respectfully submit that Claim 57 and its dependent claims are now in condition for allowance.

1 Patentability of Independent Claim 58

2 Independent Claim 58 generally includes the recitation of Claim 21, except that it now recites
3 that the life size model is of an infant head. With respect to independent Claims 1 and 21 (page 2 of
4 the Office Action), the Examiner has asserted that Gain teaches a model of a human head and
5 references column 5, lines 43-67 of Gain. However, Gain does not teach or suggest an artificial
6 cranium of an infant head. Thus, applicants respectfully submit that Claim 58 is in condition for
7 allowance.

8 In consideration of the amendment to the claims and the Remarks set forth above, it is
9 applicants' position that all claims in the current application are patentable over the art of record.
10 The Examiner is thus requested to pass this case to issue without further delay. In the event that any
11 other issues remain, the Examiner is invited to telephone applicants' attorney at the number listed
12 below.

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14 Respectfully submitted,

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17 /mike king/
18 Michael C. King
19 Registration No. 44,832

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